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10/783,522

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Roy Lurie

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10/27/2009

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EXAMINER

WHALEY, PABLO S

ART UNIT

PAPER NUMBER

1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/783,522 | Applicant(s) LURIE ET AL. | |
| | Examiner PABLO WHALEY | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 37-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/14/2009 has been entered.

Status of Claims

Claims 1-50 are currently pending.

Claims 1-36 are under consideration.

Claims 37-50 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Claim 51 is cancelled.

Application Data Sheet

The Supplemental Application Data Sheet filed 06/15/2009 has been entered.

Withdrawn Rejection

The rejection of claims 12-21 under 35 U.S.C. 101 is withdrawn in view of applicant's amendments filed 08/14/2009.

The rejection of claims 1, 12-19, 21, 24, 28, and 31 under 35 U.S.C. 103(a) as being made obvious by Potts et al. (US Pat. No. 6,882,940; Filed Aug. 10, 2001), in view of Fox et al. (Published 22 May 2003; IDS filed 11/8/2004) is withdrawn in view of applicant's amendments filed 08/14/2009.

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The rejection of claims 1-30 and 32-36 under 35 U.S.C. 103(a) as being made obvious by Goryanin et al. (Bioinformatics, 1999, Vol. 15, No. 9, p.749-758), in view of Bubendorf et al. (Journal of Pathology, 2001, Vol. 195, p.72-79) is withdrawn in view of applicant's amendments filed 08/14/2009.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1-3, 5-14, 16-23, 25-30, 32-36 are rejected under 35 U.S.C. 103(a) as being made obvious by Yao et al. (IEEE International Conference on Control Applications, Sept. 2000, p.1-21), in view of Rice et al. (US 2002/0091666, Published: July 11, 2002; Filed: July 2, 2001).

The amended claims are now drawn to a method, apparatus, and computer-readable medium holding instructions executable in a computing device, the instructions when executed causing at least one computing device to: generate a result from executing a block diagram model of a biological process by performing a simulation of the block diagram model with a simulation engine; store a simulation context of the simulation by registering an area of memory that constitutes the simulation context; gather data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted; compare the generated result to the data gathered from the experimental device using an analysis environment that is in communication with the simulation engine; and modifying modify the model of the biological process based on the comparison to correct the model of the biological process.

Yao teaches a real-time software environment (RTLTL) for data acquisition and simulation [p.2]. In particular, the RTLTL environment is in communication with a simulation software program (SIMULINK) [Abstract and p.5, ¶4]. SIMULINK is a block diagram model for simulating dynamic systems and generating results [p.2, 13-14, Example: PD Control, and Fig. 3]. Yao provide detailed discussion on steps for creating, defining, and saving block routines and simulation parameters within SIMULINK [p.15-17, Steps 2, 3, and 4], which meets the limitation for storing a simulation context of the block diagram model in view of the specification [p.35]. Furthermore, the RTLTL uses scripts to ensure that all files are saved in the appropriate directories [p.7, last ¶], which inherently shows registering an area of memory. Yao shows typical system designs wherein experimental data is transferred to a computer for analysis [p.3, ¶3], and shows the RTLTL system comprises I/O channels as well as hardware adapters for obtaining signals from external devices [p.7, p.8, Fig. 2], which is interpreted to meet the

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limitation for gathering data from an in situ experimental device. Users can easily modify the block diagrams using SIMULINK, and can modify model parameter values and blocks using the interface [p.5, ¶4, p.12, last ¶, p.13, ¶2]. Software coding and hardware devices for performing the above processes are described [p.7, ¶3]. Network systems with remote display capabilities are also described [p.4, last ¶].

Yao does not teach comparing a generated result to the data gathered from an experimental device using an analysis environment that is in communication with the simulation engine, as in claims 1, 12, 22, and 28.

Yao does not teach gathering data from a microarray or gene chip, as in claims 10, 11, 20, and 21.

Yao does not teach modifying the model of a biological process based on a comparison to correct the model of the biological process, as in claim 1, 12, 22, and 28.

Computer-based methods and systems for modeling biological processes using data gathered from an experimental device would have been well known at the time of the instant invention. In particular, Rice describes modeling platforms, including SIMULINK, and devices that output gene-array data for purposes of modeling [0018, 0048, 0052, 0069, 0095, and Fig. 1]. Data collection from gene-chips is also described [0079]. In addition, Rice shows techniques for comparing models and creating new models by modifying old models using an overlay technique based on differences, and using experimental data [Abstract, 0043, 0066, 0067, 0100]. Exemplary simulation systems operate in networked environments and can be connected remotely using various communication links [0050].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the method and system of Yao by comparing a generated result to data gathered from an experimental device using an analysis environment that is in communication with the simulation engine, as in claims 1, 10, 11, 12, 20, 21, 22, and 28, since Yao provides an analysis environment and simulation software that allows for input from external devices, as set forth above, and since Rice shows discloses devices that output biological data for purposes of modeling [0018, 0048, 0052, and Fig. 1].

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The motivation would have been to improve the knowledge of dynamic biological processes, as suggested by Rice [0008].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the method and system of Yao by modifying the model of a biological process based on a comparison to correct the model of the biological process, as in claim 1, 12, 22, and 28, since modeling of dynamic processes is well known, as shown by Yao, and since Rice explicitly shows modeling biological processes with predictable results, as well as comparing models and creating new models by modifying old models using experimental data [Abstract, 0043, 0066, 0067]. The motivation would have been to improve models through error minimization, as shown by Rice [0066].

Claims 4, 15, 24, and 31 are rejected under 35 U.S.C. 103(a) as being made obvious by Yao et al. (IEEE International Conference on Control Applications, Sept. 2000, p.1-21), in view of Rice et al. (US 2002/0091666, Published: July 11, 2002; Filed: July 2, 2001), as applied to claims 1-3, 5-14, 16-23, 25-30, 32-36, above, and further in view of Potts et al. (US 6,882,940; Filed Aug. 10, 2001).

Yao and Rice make obvious a method, device, and computer readable medium for simulating data in an analysis environment, as set forth above. In addition, Rice shows techniques for modifying models based on calculating difference using experimental data [Abstract, 0043, 0066, 0067], and data processing techniques that include the use of thresholds [0100].

Yao and Rice do not teach generating an event signal when the difference between the result and data gathered from the device exceeds a threshold, as in claims 4, 15, 24, and 31.

Potts teaches a prediction system with a modeling environment that allows for user-settable threshold levels [Col. 13, lines 20-25] and functionality for generating an alert signal when a measured signal is outside of the predetermined range of values [Co. 7, lines 20-23].

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It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the method and system made obvious by Yao and Rice by generating an event signal when the difference between the result and data gathered from the device exceeds a threshold, as in claims 4, 15, 24, and 31, since Rice employs thresholds for data processing [0100], and since system generates a warning box to notify the user if there are any errors in the SIMULINK model [p.12, ¶3], and since Potts provides software programming for generating an alert signal when signals are outside of threshold ranges, with predictable results [Co. 7, lines 20-23]. The motivation would have been to improve simulation by generating warning messages when there are errors during simulation, as suggested by Yao [p.12].

Response to Arguments

Applicant's arguments, filed 08/14/2009, that Potts and Goryanin do not teach storing a simulation context of the simulation by registering an area of memory that constitutes the simulation context, have been fully considered but are moot in view of the new grounds of rejections.

Provisional Obviousness-Type Double Patenting Rejection

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321 (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R.

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1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claims 1, 12, 22, and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 3 of copending Application No. 10/783552 in view of Rice. Both the instant claims and the copending claims recite limitations drawn to block diagrams, a simulation engine, and analysis environment. Although the conflicting claims are not identical, they are not patentably distinct from each other. In particular, the copending claims are drawn to simulations of a species of the instant claims, wherein the species “chemical reactions” are a species of biological process. Furthermore, while the copending claims do not recite gathering data from an in situ device, this limitation would have been obvious to one of ordinary skill in the art in view Rice, as set forth above. The motivation would have been to improve the knowledge of dynamic biological processes, as suggested by Rice [0008].

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner

Art Unit 1631

/PW/

/SHUBO (Joe) ZHOU/

Primary Examiner, Art Unit 1631